

Applicants: Robert J. Winchester, et al.  
U.S. Serial No.: 09/500,746  
Filed: February 9, 2000  
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#### **REMARKS**

Claims 18 and 19 are pending and under examination. No claim has been added, cancelled or amended herein.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the October 27, 2003 Advisory Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same. Applicants only address below the Examiner's remarks in the Advisory Action.

#### **The Claimed Invention**

This invention provides a composition comprising (a) an amount of a bicyclam capable of inhibiting the activation of the CXCR4 receptor by SDF-1, and (b) a pharmaceutically acceptable carrier, wherein the composition is indicated for treating rheumatoid arthritis.

#### **The Advisory Action**

In the Advisory Action, the Examiner asserts that proposed claim 18 is indefinite under 35 U.S.C. §112, second paragraph, as the phrase "indicated for treating rheumatoid arthritis" is allegedly unclear. Specifically, the Examiner queries how the status of being "indicated" would be communicated, e.g. via a label or instructions. The Examiner also maintains that the recitation of that phrase constitutes the addition of new matter, since allegedly there is no support for it in the specification.

In response, applicants respectfully traverse.

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First, it is common knowledge that therapeutic indications for pharmaceutical compositions are routine, and indeed, *required*, and that such indications must appear in written form as part of the packaging containing the composition. Applicants maintain that the phrase "indicated for treating rheumatoid arthritis" would clearly mean the existence of such writing (whether a label and/or separate instructions) as part of the instant composition's packaging. It is unnecessary for the words "label" or "instruction" to appear in the claim for this meaning to be clear.

Second, applicants maintain that the notion of the instant composition's being "indicated" for treating rheumatoid arthritis is inherent in the language "composition for treating rheumatoid arthritis" which appears, *inter alia*, in originally filed claim 7. Applicants are unaware of any other reasonable interpretation of the phrase "for treating." Due to this inherency, the language of claim 18, as amended, finds support in the specification. It is noted, of course, that verbatim support for an amendment is not required to satisfy 35 U.S.C. §132(a).

In view of the above remarks, applicants maintain that claims 18 and 19 satisfy the requirements of 35 U.S.C. §112, second paragraph.

#### **Summary**

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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No fee, other than the enclosed \$440.00 sum, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

A handwritten signature in dark ink, appearing to be 'John P. White', written over a horizontal line.

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